



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Georg **BERGER**, Andrea **SPITZER**, Christian **JAEGER**,

Jutta **PAULI** and Renate **GILDENHAAR**

Application No.: **10/689,219**

Filed: **October 20, 2003**

For: **BONE REPLACEMENT MATERIAL COMPRISING CRYSTALLINE  
AND X-RAY AMORPHOUS PHASES**

Attorney Docket No.: **3975.026**

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97 and §1.98**

**Mail Stop \_\_\_\_\_**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 56, Applicants hereby notify the U.S. Patent and Trademark Office of the following documents for the above-identified application which were cited in the specification of the present invention and/or by the Examiner in the corresponding German application. Copies of the documents set forth below and listed on the attached Form PTO-1449, are provided herewith.

1. European Patent Application No. 0 237 043 B1

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2. European Patent Application No. 0 541 546 B1
3. German Patent Application No. DE 197 44 809 C1
4. World Patent No. 91/07357
5. U.S. Patent 6,117,456

**Document 1**

The relevancy of Document 1 is discussed at paragraph 2 of the present specification. Applicants are not aware of any English language document corresponding to Document 1, but an English language abstract is attached.

Document 1 concerns a sheet material which contains calcium phosphate and which is compatible with a biological medium. It consists of a main body which contains, as main constituent, calcium orthophosphate and on which there is situated at least one outer sheet releasing calcium ions, the release of calcium from the sheet being greater than the release of calcium from the main body. The sheet material, which can be used as a temporary or permanent bone replacement substance, is produced by treatment with an acid or application of a sheet containing calcium compounds and subsequent heating between 400 and 1000°C.

**Document 2**

The relevancy of Document 2 is discussed at paragraph 3 of the present specification. Applicants are not aware of any English language document in the patent family of Document 2, other than Document 4 which is in the family and contains an English language abstract.

**Document 3**

Document 3 is cited in the German Examination report as being relevant as technical background. Applicants are not aware of any English language document corresponding to Document 3, except for an English language abstract which is attached.

Document 3 discloses a porous, rapidly soluble, glass ceramic comprises  $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$ ,  $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$  or  $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$  as the main crystal phase. A porous, rapidly soluble, glass ceramic containing  $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$ ,  $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$  or  $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$  as the main crystal phase has the following characteristics: (a) a boron content of 0.05-2 wt.%; (b) open pores with 33-80% overall porosity; (c) a pore diameter of 0.2-50  $\mu\text{m}$ ; (d) a solubility of 300-4000 mg/l/day under simulated physiological conditions in 0.2M Tris-HCl buffer at 37 deg C and pH 7.1-7.5; (e) a chemical stability at a pH above 8; and (f) a surface area (BET) of 1-40  $\text{m}^2/\text{g}$ . An Independent claim is also included for the preparation of the glass ceramic.

**Document 4**

Document 4 is cited in the German Examination Report as being relevant because of technical background. Applicants are not aware of any English language document corresponding to Document 4, except for an English language abstract which is attached.

Document 4 discloses a vitreous or vitreous-crystalline, rapidly dissolving material having the following composition (wt.%) before combustion: 20 - 55 CaO, 5 - 25 Na<sub>2</sub>O, 0.01 - 15

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K<sub>2</sub>O, 0 - 15 MgO, 30 - 50 P<sub>2</sub>O<sub>5</sub>, 0 - 15 SiO<sub>2</sub>, 0 - 40 Na<sub>2</sub>SO<sub>4</sub> and/or K<sub>2</sub>SO<sub>4</sub>. The new material can be obtained in vitreous or vitreous-crystalline form, depending on the cooling conditions. As a spontaneously crystallized glass ceramic, it contains the rhenanite phase, 'A' phase, 'X' phase and/or their mixed crystals. The material is both bioactive and biocompatible and dissolves rapidly. It can be used directly and with other materials as an implant for temporary bone replacement and to induce growth of connective tissue, and as a fertilizer and fodder material.

The present Information Disclosure Statement is being filed after three months from the application's filing date but before the mailing date of the first Office Action on the merits, therefore no Certification Under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

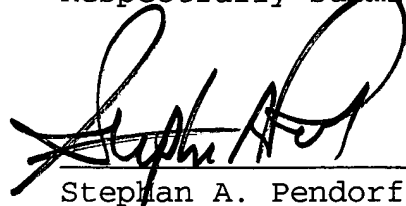
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedated or otherwise remove any listed document as a competent reference against the claims of the present application.

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Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

  
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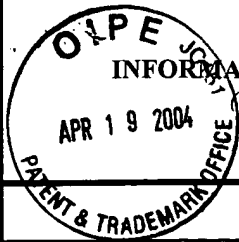
Dated: **April 15, 2004**

**CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE**

I hereby certify that the foregoing INFORMATION DISCLOSURE STATEMENT Form PTO-1449, including five (5) documents, for U.S. Application No. 10/689,219 filed October 20, 2003, were deposited in first class U.S. mail, postage prepaid, P.O. Box 1450, Alexandria, VA 22313-1450, on **April 15, 2004**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application, except for the issue fee, without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

  
Stephan A. Pendorf

**INFORMATION DISCLOSURE CITATION***(Use several sheets if necessary)*

Docket Number (Optional)

3975.026

Application Number

10/689,219

Applicant(s)

Georg Berger et al.

Filing Date

10/20/2003

Group Art Unit

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,117,456	9/12/2000	Lee et al.	A61K	47/02	

**FOREIGN PATENT DOCUMENTS**

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		0 237 046 B1	6/3/1992	Europe	A61L	27/00		✓
		0 541 546 B1	10/5/1994	Europe	C03C	3/16		✓
		197 44 809 C1	7/1/1999	Germany	C03C	10/02		✓
		91/07357	5/30/1991	World	C03C	3/16		✓

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*


EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.